# Development Of An Initial Item Bank For A New Patient-Reported Outcome Measure For Cardiac Rehabilitation (PROM-CR)

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## ABSTRACT

**Background:** A Scotland-wide government scoping exercise identified the need for a new patient-reported outcome measure (PROM-CR) for use across the wide range of cardiac diagnostic groups now accessing cardiac rehabilitation (CR).

**Aim:** The overall aim of this study was to develop a new PROM for CR. This paper describes development of the initial item bank for a first draft tool (PROM-CR1).

**Methods:** Findings from a literature review of existing PROMS, and a qualitative methodology comprising four focus groups and 12 semi-structured interviews (involving 19 CR staff and 22 service users), were combined to develop PROM-CR1's framework and the construct indicators forming its initial item bank.

**Results:** PROM-CR1's initial bank contains 40 items arranged across four conceptual ideas (domains) of health: 'general health', 'physical', 'social', 'psychological' and 'therapeutic'.

**Future Directions:** The item bank will be validated with CR staff and service users, and the tool refined for piloting within CR.

**Key Words:** Patient-reported outcome measures, cardiac rehabilitation, quality of life

## 1. INTRODUCTION

The Scottish Government's (2014) Heart Disease Improvement Plan advocated modernisation of cardiac rehabilitation (CR) services to meet its 2020 Vision: *"All patients with heart disease should be supported by CR to live longer, healthier and independent lives".* To facilitate the process, a Scotland-wide scoping exercise was undertaken (Divers, 2015), which found that CR services lack robust outcomes measures.

Patient-reported outcome measures (PROMs) provide validated evidence of health and quality of life (QoL), allowing service users to act as their own 'gold standard', and report upon outcomes that they consider important (Appleby and Devlin, 2010). As PROMs data predict mortality, cardiovascular events, hospitalisation, and cost of care, the scoping exercise recommended that the CR community should define a new PROM to help measure the health impact of rehabilitation (Divers, 2015).

Within the field, there are many different generic and disease-specific health and QoL assessment tools demonstrating varying degrees of validity, reliability and sensitivity (Thompson et al, 2016). None have been tested across the increasing diverse range of diagnostic groups now accessing CR.

Whilst generic PROMs allow comparisons between different medical conditions, they can be too broad to fully assess the impact of one particular illness, however disease-specific PROMs, although more sensitive, can miss broader aspects of a disease (Dempster and Donnelly, 2000). For comprehensive assessment, the current recommendation in CR is to use both a generic and a disease-specific tool, which is both time-consuming and burdensome for service users and clinicians (Thompson et al, 2016).

## 2. AIM

The overall aim of this study was to develop a new CR PROM able to provide valid, reliable and sensitive health status information across a range of cardiac diagnoses.

This paper describes the processes underpinning development of the initial item bank for the first draft tool (PROM-CR1). As each step informs the next, for clarity, the results of each step follow immediately after its methodology.

## 3. STUDY DESIGN (Fig. 1)

This paper describes the first four steps of a seven-step survey design process (Gehlbach et al, 2010). In step one, a literature review was undertaken to identify existing PROMs used within CR, to help establish the overall construct of PROM-CR1 and identify initial conceptual ideas of interest. To ensure a critical overview, psychometric properties of these tools were examined (Appleby and Devlin, 2010).

For step two, conceptual ideas identified from the literature review were used to guide a qualitative data collection methodology. Focus groups and individual semi-structured interviews were used to ascertain how CR staff and service users verbalise their perceptions of the impact of a cardiac diagnosis upon health and QoL. Focus groups were held first to allow group interactions to stimulate a breadth of comparable and contrasting perceptions (Morgan, 1997; Webb, 2002). These data were explored in more depth within semi-structured interviews, to obtain completeness of data (Morgan, 1997).

In steps three and four, qualitative data were combined with literature review findings to establish PROM-CR1's conceptual framework and domains, and the construct indicators informing its initial bank of items. Steps five (expert validation) and six (service user interpretation) will refine the item bank in preparation for piloting PROM-CR's validity and reliability within CR (step seven).

## 4. STUDY LOCATION AND ETHICAL APPROVAL

The study was reviewed and approved by the XXXX [REC ref.XXXX; IRAS project ID:XXXX], and Research and Development department within XXXX. All participants provided written, informed consent, and all procedures were undertaken within XXXX between February and September 2016 by two researchers: a main researcher (consultant physiotherapist with vast clinical and research experience within CR),

and an assistant researcher (assistant psychologist working within the CR team). They formed a project steering group with a further four clinicians not directly involved in data collection: a cardiac nurse consultant, a cardiologist, a clinical psychologist and a senior nursing lecturer. The study conforms to principles outlined in the Declaration of Helsinki (World Medical Association, 1964).

## 5. STEP ONE – LITERATURE REVIEW

### 5.1 Methodology

A systematic search of the PubMed database was undertaken by the assistant researcher to identify generic and disease-specific PROMs used within CR using the following key words: "*health-related quality of life questionnaire*" AND "*heart*" OR "*heart disease*" OR "*cardiac" OR "cardiac rehabilitation".* A second search of PubMed was undertaken to identify articles evaluating psychometric properties of the selected tools, using full and abbreviated names of the tools in combination with: "*psychometric properties*" OR "*validity*" OR "*reliability*" OR "*sensitivity"* OR *"development"* AND "*heart disease*" OR "*cardiac*" or "*heart*". The entire search methodology was replicated by the main researcher to ensure no key articles were omitted. All duplicates were removed.

To be included in the review, articles were required to meet the following criteria:

- Published in English
- Examining tools:
    - measuring more than one domain of health or QoL
    - tested in adults (aged ≥18years) with a cardiac diagnosis initiating CR referral (myocardial infarction [MI], cardiac surgery, percutaneous coronary intervention [PCI], stable angina pectoris [AP], arrhythmias, heart failure [HF], or implanted devices)

## 5.2 Results

As shown in **fig. 2a**, 14 tools (five generic and nine disease-specific) were identified. Characteristics, measurement domains and the diagnostic groups in which the tools have been tested are shown in **table 1**. As shown in **fig. 2b**, 54 articles examining the tools' psychometric properties were identified, and used by the assistant researcher critiqued the tools against recognised criteria (Mackintosh et al, 2009). The process was verified by the main researcher. As shown in **table 2**, across the generic tools, the Medical Outcomes Short Form-36 [SF-36] (Ware and Sherbourne, 1992) met the criteria most closely; certainly, although complicated to score and analyse, the SF-36 is the recommended generic tool for use in CR (Thompson et al, 2016).

Within the disease-specific tools, there was variation across the criteria, and none demonstrated favourable evidence in relation to floor/ceiling effects. The MacNew Heart Disease Quality of Life Tool [MacNew] (Höfer et al, 2004), Kansas City Cardiomyopathy Questionnaire [KCCQ] (Green et al, 2000) and Minnesota Living with Heart Failure Questionnaire [MLHFQ] (Rector et al, 1987) demonstrated most favourable evidence. As the KCCQ and MLHFQ are designed for use in HF, and the MacNew has only been tested in those with a diagnosis of MI or AP, the appraisal confirmed the need for a new PROM which can be applied across a wider range of cardiac diagnoses.

The main and assistant researchers examined the conceptual ideas within the existing tools, for potential use in guiding the qualitative data collection methodology (**table 1**). They agreed that the most prevalent conceptual ideas ('general health', 'physical', 'social' and 'psychological') should be used as qualitative prompts, but to enable others to emerge, agreed to include an open prompt around 'other factors' influencing health and QoL.

# 6. STEP TWO – QUALITATIVE DATA COLLECTION

## 6.1 Methodology

### 6.1.1 Sample and Recruitment

#### *6.1.1.1 Staff*

By email, the main researcher invited all 61 clinicians and support staff within the cardiology managed clinical network (MCN) in XXXX to participate in the focus groups. Of the 17 who expressed interest, 15 were able to attend. Following the groups, a further four staff members from the MCN, purposefully identified to include a range of professions, were invited by the main researcher to participate in individual semi-structured interviews. All four agreed to take part.

#### *6.1.1.2 Service Users*

Within XXXX, all CR service users are asked to verbally consent to being added to a CR database which may be accessed by clinicians for correspondence. In batches of 50, the main researcher identified CR service users most recently added to the database, fulfilling the following criteria:

*Inclusion Criteria*

- Cardiac event (MI, cardiac surgery, PCI, AP, arrhythmia, HF, implanted device) within past six months
- Aged ≥18 yrs

*Exclusion Criteria*

- Physical/mental impairment realistically preventing data collection
- Documented evidence that service user not informed of diagnosis (e.g. due to physical/mental impairment)

The assistant researcher sent all a letter of invitation with tear-off slip (to confirm/refute interest within two weeks), study information sheet, and SAE. From the first two batches of 50 service users (i.e. 100 in total), 28 were willing to participate.

Of the 28, the first 20 to reply were invited by the assistant researcher by telephone to participate in two initial focus groups and 14 were available to attend. The remaining six agreed to be held in reserve, along with the other eight willing service users – and of those, eight were contacted (purposefully, to include a range of cardiac diagnoses) to participate in semi-structured interviews. All eight agreed. Immediately before every focus group and interview, there was time for further discussion about the study, and for provision of informed, written consent.

### *6.1.2 Focus Group Procedures*

All focus groups were held in meeting rooms at clinical sites within NHS Ayrshire and Arran. Staff and service users attended separate focus groups, to enable comparable and contrasting opinions from the two groups to emerge (Webb, 2002). Of the 15 staff recruited, six participated in the first focus group, and nine in the second. Of the 14 service users recruited, seven participated in the first focus group, and seven in the second. The researchers agreed that at least two of each type of group would be held to reduce the possibility of obtaining skewed data from one 'stand alone' group, and that groups would continue to be arranged until there was data saturation (Morgan, 1997).

All focus groups were facilitated by the assistant researcher, whilst the main researcher took notes throughout. Both were familiar to clinicians participating in the groups (beneficial in encouraging the 'flow' of discussion between colleagues), yet had not been involved in the care of any of the service users (ensuring unbiased opinions).

All groups were audio-recorded and all participants were assured that the all discussions would remain anonymous. The assistant researcher began each focus group reiterating the study purpose, and explaining the discussion format and main question to be answered: *"How does diagnosis of a cardiac condition impact upon someone's health and QoL?"* [staff], or *"How has your diagnosis of a cardiac condition impacted upon your health and QoL?"* [service users]. Initial conceptual ideas identified from the literature review prompted discussions around: perceptions/definitions of general health and QoL, and physical, social, psychological

and 'other' factors influencing health and QoL after a cardiac diagnosis. Average focus group duration was 57 minutes (range 49-72 minutes).

### *6.1.3 Semi-Structured Interview Procedures*

All individual, semi-structured interviews with four staff and eight CR service users were conducted in meeting rooms at clinical sites within NHS Ayrshire and Arran. All interviews were audio-recorded, and were facilitated by the assistant researcher, who assured participants that all discussions would remain anonymous.

The assistant researcher began every interview reiterating the purpose of the study, and explaining the discussion format and main question to be answered: *"How does diagnosis of a cardiac condition impact upon someone's health and QoL?"* [staff], or *"How has your diagnosis of a cardiac condition impacted upon your health and QoL?"* [service users]. As with the focus groups, conceptual ideas identified from the literature review formed the basis of an interview schedule used with both staff and service users, incorporating: perceptions/definitions of general health and QoL, and physical, social, psychological and 'other' factors influencing health and QoL after a cardiac diagnosis.

For staff, the schedule was tailored to each profession, to help different professional perceptions to emerge (as an example, the dietetic schedule is shown in **table 3**). Within both service user focus groups, participants often discussed the importance of understanding their cardiac diagnoses. To further explore this, an additional question was added to both types of schedule (**table 3**): *"To what extent would you say that it's important for someone to have a good understanding of his/her diagnosis?"* [staff], or *"To what extent would you say that it is important to have a good understanding of your diagnosis?"* [service users]. Average interview duration was 33 minutes (range 25-48 minutes).

### *6.1.4 Qualitative Data Analysis*

After every focus group and interview, the recording was transcribed and the written transcription analysed using a three-stage constant comparison method (Strauss

and Corbin, 1999): stage 1 - data chunked into small units and coded, stage 2 – codes grouped into categories ('sub-themes'), and stage 3 – 'key themes' identified expressing the content of the codes within sub-themes. This process was undertaken by the assistant researcher and discussed and negotiated with the main researcher. Although the researchers ensured that data analysis of one group/interview did not force the direction of subsequent discussions, data generated contributed to subsequent prompting, where appropriate. This process enabled researchers to identify the need to incorporate the question on understanding a cardiac diagnosis within the interview schedules, and to identify that data saturation had occurred after two of each type (staff and service user) of focus group, and after four staff and eight service user semi-structured interviews.

## 6.2 Results

### *6.2.1 Participant Characteristics*

Details of all participants are shown in **table 4**.

### *6.2.1 Summary of Key Themes*

Three key themes (and their sub-themes) identified from the data - 'expectations and entitlement' ('self', 'others'), 'adjustment and acceptance' ('diagnosis', 'lifestyle changes', 'confidence loss') and 'control and choice' ('daily life and health' and 'care') - are shown in **table 5**, evidenced by relevant quotes from staff and service user participants.

#### *6.2.1.1 Expectations and Entitlement*

Across focus groups and interviews, many staff and service users acknowledged that everyone is entitled to have, and expects, a 'good' QoL, often described as 'feeling well' or being 'in good health'. Many participants discussed expectations that service users place upon themselves after a cardiac diagnosis – how they compare their abilities to undertake everyday tasks and return to work and hobbies, to their pre-diagnosis abilities.

Although only mentioned by a few staff, many service users described frustration and a sense of failure resulting from this constant comparison, and described how perceived expectations of others compound these feelings. Often there was worry around employers' expectations about return to work and job security, and around family and friends treating them differently, causing relationship tensions and feeling burdensome to others.

#### *6.2.1.2 Adjustment and Acceptance*

Many service users and staff discussed difficulties in adjusting to, and accepting, a cardiac diagnosis, with several stating that the service user often blames himself/herself, or others. Several staff and service users described how worrying about the impact of the diagnosis, their recovery potential, and the stress that the diagnosis places upon their families and friends, can make them anxious, tearful or depressed. Only the service users verbalised the importance of having 'enough' knowledge and understanding about their condition to help them accept their diagnosis.

Numerous participants discussed the impact of lifestyle changes imposed by a cardiac diagnosis. Many recognised the wide-ranging physically limiting impact - cardiac symptoms (pain, shortness of breath, fatigue), altered appetite, poor sleep quality, feeling 'slowed down', and loss of libido – and several staff explained how physical anxiety symptoms are often mistaken for cardiac symptoms – intensifying anxiety symptoms, and causing confidence loss. Several service users described their subsequent apprehension about going out alone, or travelling away from home.

In addition to imposed lifestyle changes, both staff and service users acknowledged challenges associated with adhering to recommended changes – a healthier diet, smoking less and consuming less alcohol – with many explaining how these can cause social withdrawal, and isolation. Both staff and service users recognised the limiting effect of being unable to maintain a previous role community role, or to drive or work post-diagnosis, with financial constraints caused by loss of earnings further limiting socialisation. Although not mentioned by staff, in addition to anxiety around

holiday travel, a few service users verbalised frustration about travel insurance restrictions.

#### *6.2.1.3 Control and Choice*

Several staff and many service users recognised the importance of having control and choice; it was considered an entitlement for every person to have control over his/her daily life. Many staff and service users recognised the value of being able to control their preferred daily structure and routine. A few emphasised a desire to be able to change this structure spontaneously, without having to consider the impact upon their condition.

Several service users described their difficulties in adjusting to losing control over their heart and health, and many staff explained how a key goal of CR is to help service users regain this control. Both staff and service users discussed the importance of having 'enough' healthcare support, and several service users highlighted the importance of being able to ask questions to feel involved in their care and more in control of their condition.

## 7. STEP THREE – COMBINING THE DATA

### 7.1 Methodology and Results

In discussion with the steering group, the researchers merged conceptual ideas from the literature review with qualitative data to develop a list of 40 construct indicators (**table 5**). Every key and sub-theme identified within the qualitative data was aligned with the conceptual idea (prompt) within which the data was most frequently generated. Themes were evidenced with the quotes from staff and/or service users that the researchers agreed were most reflective of the context of, and language used to describe, the data. Although some data were generated solely by service users (**table 5**), these were included to ensure that no important data were missed from the list of indicators. Certainly, service users are PROM-CR1's target audience, and steps five and six of the design process will ascertain staff and service users' perceptions of content relevance (Gehlbach et al, 2010). To optimise respondent

comprehension of the initial item bank, where possible, the list of construct indicators was developed using the language within the quotes (Bowling, 2005).

## 8. STEP FOUR – DEVELOPING DOMAINS AND ITEMS

### 8.1 Methodology and Results

In developing the item bank, the researchers arranged the 40 construct indicators into potential domains. Initial domains agreed were 'physical', 'social' and 'psychological' conceptual ideas identified from the literature review – each containing its aligned indicators from **table 5**. Notably, only indicator [1] was aligned to the conceptual idea of 'general health', which the researchers agreed was due to little variation in verbalisation of 'feeling well' and being 'in good health'. The researchers thus agreed that the tool should open with an 'overall health and well-being score'. Accordingly, and to enable identification of whether items within each domain accurately reflect the overall perception of that aspect of health/QoL, an overall score was added to 'physical', 'social' and 'psychological' domains.

As indicators [15], [39] and [40] were developed from qualitative data emerging around 'other' factors influencing health/QoL, the researchers agreed that these should form a 'therapeutic' domain, encompassing knowledge and understanding, control, involvement in care and support. Indicators [37] and [38] were also thought to fit within 'therapeutic', and were subsequently moved from 'psychological'.

Although items as statements are often criticised for failing to represent a 'natural' conversation (Gehlbach et al, 2010), after reflecting upon existing tools, and their combined clinical experience, the steering group agreed that the MLHFQ is the most user-friendly, acceptable tool currently used within CR practice – largely due to its use of statements measured by a six-point Likert scale. The team therefore structured the 40 items as statements (retaining the qualitative language as far as possible), with which service users will rate their agreement: *1-strongly disagree* to *5-strongly agree*. Although 'not applicable' options can skew Likert scales (Bowling, 2005), including *0-n/a* was considered essential because not all items within the construct will apply to all service users.

A two-week recall was considered appropriately long to eliminate the impact of small daily health changes upon responses, yet short enough to be recalled easily (Bowling, 2005), whilst being able to detect change before and after a typical 8-12 week out-patient CR programme. A time-bound recall was deemed inappropriate for the 'therapeutic' domain, thus its items relate to 'current' perceptions. For 'physical', 'social' and 'therapeutic' domains, a higher score denotes a more negative impact upon health/QoL, whilst scoring was reversed for the therapeutic domain, and for the overall summary scores, to reduce acquiescence bias (Bowling, 2005; Gehlbach et al, 2010). Scale performance will be fully examined within the pilot.

**Appendix A** contains PROM-CR'1 initial item bank, arranged in domains, and with scales. Although lengthy in its current state, it is hoped that a more streamlined tool will emerge through steps five to seven of the design process.

## 9. DISCUSSION

To develop an initial item bank for the first draft of PROM-CR1, a literature review of existing tools was undertaken and its findings combined with qualitative data from staff and service users. Though the literature review did guide the qualitative methodology, notably the qualitative data were largely reflective of those measured across existing tools.

However, unlike several others (Seattle Angina Questionnaires [SAQ] (Chan et al, 2014; Spertus et al, 1995), Cardiovascular Limitations and Symptoms Profile [CLASP] (Lewin et al, 2002); Chronic Heart Failure Questionnaire [CHQ] (Guyatt et al, 1989), PROM-CR1's initial item bank does not include assessment of any particular cardiac symptom. Perhaps because of the range of diagnoses of the service user participants, and because staff participants typically care for a diverse range of cardiac conditions, there was little qualitative discussion on specific symptoms. Certainly, this is probably out with the scope of a tool designed for use across a variety of cardiac conditions.

Of the conceptual ideas identified from existing tools, 'self efficacy and knowledge' (from the KCCQ) and 'disease perception' (from the SAQ) were not used as

qualitative prompts, however emerged as construct indicators and were included within the item bank. As facilitating self-management is a key goal of CR, PROM-CR1 will be useful in gauging CR's impact upon this outcome (British Association for Cardiovascular Prevention and Rehabilitation, 2017). From the 'Quality of Life Index-Cardiac [QLI-C] (Ferrans and Powers, 1985), neither 'economic' nor 'spiritual' conceptual ideas were used as qualitative prompts; whilst economic concerns emerged as construct indicators, spiritual issues were not verbalised. It is widely acknowledged that PROMs should not enquire about treatment satisfaction (Appleby and Devlin, 2010), thus this conceptual idea (used within the SAQ) was disregarded after the literature review.

The mean age and gender split of service users recruited to the qualitative methodology is fairly typical of those attending CR, however within the diagnoses, there was high proportion who had suffered an MI, and no one who had undergone elective PCI (without prior MI). The main and assistant researchers discussed the need to continue to purposefully recruit, however agreed that the range of cardiac diagnoses across those recruited were sufficiently varied to have achieved appropriate data saturation. When piloting PROM-CR1, its performance within and across the diagnostic groups will be examined. Finally, whilst the qualitative methodology did not incorporate the perceptions of those who opted out of CR input, PROM-CR1 will be predominantly used with those who are engaged with CR; nonetheless, its wording was chosen to be applicable regardless of CR uptake.

## 10. CONCLUSIONS

A literature review and qualitative data collection methodology were used to generate an initial item bank for PROM-CR1. From the literature, four conceptual ideas for health/QoL were identified: 'general health', 'physical', 'social' and 'psychological'. Qualitative data were organised in three key themes - 'expectations and entitlement', 'adjustment and acceptance', and 'control and choice'. Combining the data generated an initial item bank consisting of 40 items within 'physical', 'social', 'psychological' and 'therapeutic' domains, and with 'general health and well-being', 'physical', 'social', and 'psychological' summary scores. The item bank will now be validated with staff and service users, and refined for piloting within CR.

## 11. KEY MESSAGES

- A Scotland-wide government scoping exercise identified the need for a new patient-reported outcome measure (PROM-CR) for use across the wide range of cardiac diagnostic groups now accessing cardiac rehabilitation (CR).

- A literature review of existing tools and a qualitative data collection methodology involving CR staff and service users were used to develop the framework for a first draft of the tool (PROM-CR1) and the construct indicators forming its initial item bank.

- PROM-CR1 contains 40 items arranged across four conceptual ideas (domains) of health: ‘general health’, ‘physical’, ‘social’, ‘psychological’ and ‘therapeutic’.

- The item bank will be validated with CR staff and service users, and the tool refined for piloting within CR.

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